

SUMMARY MINUTES

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OF THE

ORTHOPEDICS AND REHABILITATION DEVICES

ADVISORY PANEL MEETING

OPEN SESSION

February 18, 2000

**9200 Corporate Blvd.
Room 20 B
Rockville, Maryland**

**Orthopedics and Rehabilitation Devices Advisory Panel Members
February 18, 2000**

Barbara D. Boyan
Panel Chair

Albert Aboulafia, M.D.
Voting Member

Jeno R. Chapman, M.D.
Consultant, deputized to vote

Thomas B. Ducker, M.D.
Consultant, deputized to vote

Cato T. Laurencin, M.D., Ph.D.
Voting Member

Harry B. Skinner, M.D., Ph.D.
Voting Member

Marcus P. Besser, Ph.D.
Consultant, deputized to vote

Janet Wittes, Ph.D.
Consultant, deputized to vote

FDA Participants

Hany Demian, M.S.
Executive Secretary
Orthopedics and Rehabilitation Devices Advisory Panel

Jim Dillard, M.S.
Acting Director, Division of General and Restorative Devices (DGRD)

Mark Melkerson, M.S.
Branch Chief
Orthopedic Devices Branch

OPEN SESSION

Panel Executive Secretary Hany Demian called the meeting to order at 9:07 a.m. and read the deputization of temporary voting members for the consultants listed on the panel roster. Mr. Demian also read the conflict of interest statements, noting that matters involving Drs. Boyan, Skinner, Laurencin, Chapman, and Yaszemski had been considered but their full participation was allowed. He asked the panel members to introduce themselves.

Panel Chair Dr. Barbara Boyan noted that the voting members constituted a quorum and introduced Mr. Mark Melkerson of the Orthopedic Devices Branch to update the panel on branch activities.

Mark Melkerson, Chief of the Orthopedics Devices Branch, gave the branch update. Concerning items from previous Advisory Committee meetings, he noted that the draft *Federal Register* notice on panel recommendations to reclassify constrained total hip arthroplasty devices is being prepared and that the branch has received positive feedback from the panel's discussion of development of computer controlled systems. The agency has also issued the reclassification final order for PMMA non- and semi-constrained shoulders. Division staffing changes noted were the appointment of James Dillard as Acting Director of the Division of General and Restorative Devices (DGRD) and of Celia Witten as Acting Director of the Division of Cardiovascular and Respiratory Devices. Mr. Melkerson announced an appointment as new Acting Orthopedic Team Leader for Ms. Jodi (Nashman) Anderson for Bone and Joint Replacement and Miscellaneous Orthopedic Devices; and he noted that the new branch chief for Osteosynthesis and Spinal Devices will not be appointed until after the ORS/AAOS

meeting. Mr. Melkerson noted two other appointments: Janine Morris as a mechanical engineer in the ORDB, and Sergio Gadaleta as a chemist in the REDB.

OPEN PUBLIC HEARING

There were no requests from the audience to address the panel.

The Open Session was adjourned at 9:20 and followed by a Closed Session.


Harry Demian, M.S.
Panel Executive Secretary

I approve the minutes of this meeting as recorded in this summary.


Barbara D. Boyan
Panel Chair

Summary minutes prepared by
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